UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,241	12/13/2001	Roland Horres	49276-262679	1968

7590 10/05/2006

GREGORY TUROCY
AMIN & TUROCY, LLP
24TH FLOOR, NATIONAL CITY CENTER
1900 EAST 9TH STREET
CLEVELAND, OH 44114

EXAMINER	
BARRETT, THOMAS C	

ART UNIT	PAPER NUMBER
3738	

DATE MAILED: 10/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/914,241	HORRES ET AL.	
	Examiner	Art Unit	
	Thomas C. Barrett	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 September 2006*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *30-49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *30-49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 6, 2006 has been entered.

Response to Arguments

Applicant's arguments with respect to claims 30-49 have been considered but are moot in view of the new ground(s) of rejection.

The Applicant argues:

"As described by the specification, the preparation of constituents of the outer layer of a blood cell and/or constituents of the outer layer of a mesothelial cell result in a final fraction that contains MULTIPLE constituents, some of which can include the subject "impurities". Whatever impurities are present in the materials are derived from the disclosed mesothelial and/or blood cells and are consistently present as the inevitable byproduct of the preferred embodiments in the specification. No experimentation needs to be done to prepare the materials required for the invention. One reasonably skilled in the art knows that impurities are present in any in situ preparation." However, the cited examples disclose only isolation of a product, e.g. erythrocyte plasma membrane heparan sulfate, not impurities.

The Applicant also states:

"A basic idea of the invention relates to transferring the glycocalyx of a mesothelial cell or a blood cell, i.e., to transfer the complete constituents (= all constituents) of the outer layer (= glycocalyx) of a mesothelial cell or of a blood cell, which have to be hemocompatible to an artificial or natural surface in order to make this surface hemocompatible. Consequently, all constituents of the outer layer (glycocalyx) of a mesothelial cell or of a blood cell are used since all these constituents have to be hemocompatible." However this "basic idea" is never disclosed or claimed in the specification as originally filed.

The Applicant argues:

"The "constituents" of the claims are adequately described in the specification in a manner so that one skilled in the art can MAKE and USE the constituents, so long as the constituents come from the outer layer of a blood cell or the outer layer of a mesothelial cell. It is not a requirement of the patent laws to know the chemical identity of every species in the invention so long as the preferred embodiment allows one to practice the invention and obtain the utility thereof." As noted above, the use of the entire glycocalyx is never disclosed, so one skilled in the art would be unable to determine the scope of the invention without undue experimentation because the Applicant fails to supply support for which, if any, additional components or "impurities" are required to make or use the present invention. The Applicant also notes that the "consisting of" transitional phrase functions to close the claim to the inclusion of materials other than those recited except for impurities ordinarily associated therewith.

However, "impurities" does not include essential material. MPEP 2173.05(b) states: "The phrase "a silicon dioxide source that is essentially free of alkali metal" was held to be definite because the specification contained guidelines and examples that were considered sufficient to enable a person of ordinary skill in the art to draw a line between unavoidable impurities in starting materials and essential ingredients." Therefore, the MPEP discloses that there is a difference between impurities and essential material, yet the Applicant is arguing the "impurities", which are not disclosed, constitute essential material.

The Applicant argues:

"In addition, the independent claims state that the hemocompatible material be derived from "constituents of the outer layer of a blood cell, constituents of the outer layer of a mesothelial cell or a combination thereof." Baumann et al only discloses material obtained from aortic endothelial cells and not from blood or mesothelial cells." As noted previously, the Applicant has failed to supply evidence to overcome the "product-by-process" limitation for the source of the constituents. The declaration of May 27, 2005 even states:

"The applicant provided the following materials to compare hemocompatibility:

Materials obtained from outer layers of erythrocytes and/or mesothelial cells

(Claimed materials)

Endothelial cell surface heparansulfate (ESHS) from bovine aortae (produced by the Applicant) = ESHS

Erythrocyte glycolcalix	= EryGlyco
Mesothelial glycocalix	= MesoGlyco "

Therefore the declaration admits ESHS as being a claimed material, equivalent to erythrocyte or mesothelial glycocalix.

The Applicant argues:

"Nevertheless, reading Baumann et al to indicate that the surface covalently modified with oligoamide spacer is equivalent to the unmodified surface of the first element of the current invention (artificial compound) is a tortured construction of what is disclosed in Baumann et al." However, oligoamide bonded to silicon constitutes an artificial compound as claimed. One can also interpret the oligoamide as the artificial compound itself, with the synthetic polymer as the substrate or "material".

In addition, Baumann et al does not expressly teach against the use of multiple constituents. Baumann et al discloses isolation of the ESHS on page 216, which the Applicant admits results in some "impurities".

In addition, the arguments of counsel cannot take the place of evidence in the record. Examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration include statements regarding ***unexpected results***, commercial success, solution of a long-felt need, ***inoperability of the prior art***, invention before the date of the reference, and allegations that the author(s) of the prior art derived the disclosed subject matter from the applicant. The "disadvantages" cited by the Applicant do not constitute a teaching away.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 30-49 remain rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. Elements critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). The Applicant's arguments of June 29, 2005 state that the differences between commercially available heparin sulfate and native heparin sulfate is their purities ***and*** distribution of molecular weights. The trace impurities of the native heparin sulfate are admitted by the Applicant and are not disclosed or claimed, nor is the distribution of molecular weights, but both are implied to be essential to the invention when compared to the commercially available product. Furthermore, the Applicant has failed to disclose which impurities or molecular weights are essential to the present invention or how they can be determined by one of ordinary skill without undue experimentation.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 30-36, 38-39, 41-47 and 49 are rejected under ***35 U.S.C. 102(b)*** as anticipated by ***or***, in the alternative, ***under 35 U.S.C. 103(a)*** as obvious over Baumann et al (Semin Thromb Hemost. Part I). Baumann et al discloses a hemocompatible surface comprising heparan sulfate, a polysaccharide constituent of an outer layer of a blood cell firmly attached to a compound. The Bauman et al implant may comprise hyaluronic acid, chondroitin sulfate, dermatan sulfate, heparan sulfate, keratin sulfate or ESHS as cited above (see "Materials and Methods"- page 205). The Baumann et al implant consists of the same materials claimed and is hemocompatible. For example, the declaration of June 29, 2005 admits the hemocompatability of the of endothelial cell surface heparan sulfate. The heparan sulfate is "isolated" (page 205).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 37, 40 and 48 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Thompson (5,718,159) in view of Baumann et al. as above. Thompson discloses a vascular graft comprising a high-molecular weight polymer (col. 7, lines 46-52) however Thompson fails to disclose the graft coated with heparan sulfate. Baumann et al teaches a hemocompatible surface comprising heparan sulfate. It would have been obvious to one of ordinary skill in the art to combine the teaching of

a heparan sulfate coating, as taught by Baumann et al, to a vascular graft as per Thompson, the motivation to combine being the coatings of Baumann et al show no platelet adhesion.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas C. Barrett whose telephone number is (571) 272-4746. The examiner can normally be reached on Mon. -Fri. from 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Thomas C. Barrett

TOM BARRETT
PRIMARY EXAMINER
TECHNOLOGY CENTER 3700